



PTO/SB/21 (08-03)

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/731,375
	Filing Date	December 8, 2003
	First Named Inventor	Philip J. BARR
	Art Unit	1614
	Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	8 pages + 22 refs.	Attorney Docket Number 368292001700

ENCLOSURES (Check all that apply)

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	MORRISON & FOERSTER LLP (Customer No. 25226) Eric H. Witt - 44,408
Signature	
Date	April 12, 2004

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PATENT
Docket No. 368292001700

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Patricia M. Ellison

Patricia M. Ellison

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Philip J. BARR et al.

Serial No.: 10/731,375

Filing Date: December 8, 2003

For: METHODS AND COMPOSITIONS FOR
TREATMENT OF OTITIS MEDIA

Examiner: Not Yet Assigned

Group Art Unit: 1614

INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Pursuant to the USPTO notice dated July 11, 2003, waiving the requirement under 37 C.F.R. § 1.98 (a)(2)(i) to provide copies of U.S. Patents and U.S. Published Applications, copies of those references are not submitted. Copies of foreign documents and non-patent literature are submitted herewith in accordance with 37 C.F.R. § 1.98 (a)(2). The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of __ is enclosed.
 - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly, no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of __ is enclosed.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does

not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 368292001700. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: April 12, 2004

Respectfully submitted,

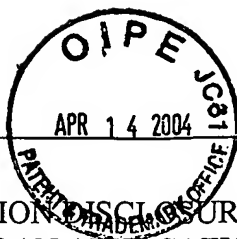
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Form PTO-1449

Docket Number 368292001700

Application Number 10/731,375

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

Applicant

Philip J. BARR et al.

Filing Date December 8, 2003

Group Art Unit 1614

Mailing Date April 12, 2004

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	04/17/2003	2003/0073217	Barr et al.			
	2.	03/22/1988	4,732,973	Barr et al.			
	3.	06/21/1988	4,752,576	Brake et al.			
	4.	04/16/1991	5,008,242	Lezdey et al.			
	5.	05/19/1992	5,114,917	Lezdey et al.			
	6.	06/08/1993	5,217,951	Lezdey et al.			
	7.	03/01/1994	5,290,762	Lezdey et al.			
	8.	05/30/2000	6,068,994	Barr			
	9.	01/16/2001	6,174,859	Lezdey et al.			
	10.	01/28/2003	6,511,960	Lezdey et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date		Country	Class	Subclass	Translation YES NO
	11.	06/12/1991	EP 0 432 117	Europe			
	12.	06/27/2002	WO 02/50287	WIPO			

OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	13.	Antonelli, P. J. et al. (2003). "Alpha1-Antitrypsin and Ilomastat Inhibit Inflammatory Proteases Present in Human Middle Ear Effusions," <i>Laryngoscope</i> 113(8):1347-1351.
	14.	Antonelli, P. J. et al. (2003). "Protease Inhibitors α_1 -Antitrypsin and Ilomastat Are not Ototoxic in the Chinchilla," <i>Laryngoscope</i> 113(10):1764-1769.
	15.	Avidano, M.A. et al. (1998). "Analysis of Protease Activity in Human Otitis Media," <i>Otolaryngol Head Neck Surg</i> 119(4):346-351.
	16.	Carrell, R. W. et al. (1982). "Structure and Variation of Human α_1 -Antitrypsin," <i>Nature</i> 298:329-334.
	17.	Galaray, R. E. (1993). "Antiinflammatory Protease Inhibitor," <i>Drugs of the Future</i> 18:1109-1111.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Docket Number 368292001700	Application Number 10/731,375
	Applicant Philip J. BARR et al.	
	Filing Date December 8, 2003	Group Art Unit 1614
	Mailing Date April 12, 2004	

18.	Grobelny, D. et al. (1992). "Inhibition of Human Skin Fibroblast Collagenase, Thermolysin, and Pseudomonas Aeruginosa Elastase by Peptide Hydroxamic Acids," <i>Biochemistry</i> 31:7152-7154.
19.	Hamaguchi, Y. et al. (1991). "The Relationship Between Proteases Activity and Glycoprotein Levels in Middle Ear Effusions from Experimental Otitis Media in Cats," <i>Acta Otolaryngol Suppl.</i> 483:23-29.
20.	Hamaguchi, Y. et al. (1992). "Neutrophil Elastase and its Complex with Alpha 1-Antitrypsin in the Pathogenesis of chronic Suppurative Otitis Media," <i>Ann. Otol. Rhinol. Laryngol. Suppl</i> 101:26-31.
21.	Hercz, A. (1985). "Proteolytic Cleavages in α_1 - Antitrypsin and Microheterogeneity," <i>Biochem Biophys. Res. Comm</i> 128:199-203.
22.	Hubbard, R. C. et al. (1989). "Recombinant DNA-Produced α_1 -Antitrypsin Administered by Aerosol Augments Lower Respiratory Tract Antineutrophil Elastase Defenses in Individuals with α_1 -Antitrypsin Deficiency," <i>J. Clin. Invest</i> 84:1349-1354.
23.	Levy, D. E. et al. (1998). "Matrix Metalloproteinase Inhibitors: A Structure-Activity Study," <i>J. Med. Chem.</i> 41:199-223.
24.	Ohyama, M. et al. (1999). "Ofloxacin Otic Solution in Patients with Otitis Media," <i>Arch Otolaryngol Head Neck Surg</i> 125:337-340.
25.	Otlewski, J. et al. (1999). "Protein of Serine Proteinases," <i>Acta Biochimica Polonica</i> 46:531-565.
26.	Pearson, W. R. et al. (1998). "Improved Tools for Biological Sequence Comparison," <i>PNAS</i> 85:2444-2448.
27.	Potemka, J. et al. (1994). "The Serpin Superfamily of Proteinase Inhibitors: Structure, Function, and Regulation," <i>J. Biol. Chem.</i> 269:15957-15960.
28.	Roland, P. S. (2002). "Chronic Suppurative Otitis Media: A Clinical Overview," <i>Ear Nose and Throat J.</i> 81 (Suppl. 1): 8-10.
29.	Tierney P. et al. (1995). "Neutrophil Elastase-Alpha 1-Antitrypsin in Middle Ear Fluid in Chronic Otitis Media with Effusion," <i>Clin Otolaryngol.</i> 20(3):230-233.
30.	Travis, J. et al. (1985). "Isolation and Properties of Recombinant DNA Produced Variants of Human α_1 - Proteinase Inhibitor," <i>J. Biol. Chem</i> 260(7):4384-4389.
31.	Wilmoth, J. G et al. (2003). "Tympanic Membrane Metalloproteinase Inflammatory Response," <i>Otolaryngol Head Neck Surg</i> 129(6):647-654.
32.	Wilmoth, J. G. et al. (2003). "Matrix Metalloproteinase in a Gerbil Cholesteatoma Model," <i>Otolaryngol Head Neck Surg</i> 129(4):402-407.

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EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.	